

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### phase I clinical trial placental mesenchymal stem cell therapy for the treatment of type 1 diabetes mellitus

#### Protocol summary

##### Study aim

main goal is to access the safety of treatment with placental mesenchymal stem cell in new onset T1DM patients.

##### Design

10 eligible new onset T1DM patients with 12-18 yr age will be enrolled in this phase one clinical trial. no blinding and single group clinical trial will be done and placental mesenchymal stem cell will be transplanted with clinical grade standard .

##### Settings and conduct

new onset T1DM patients with less than 6 month from Diagnosis will be enrolled. intravenous injection of clinical grade placental mesenchymal stem cell-which cultured in endocrinology and metabolism research institute- will be done after taken inform consent from patients in children medical center . before and after placental mesenchymal stem cell transplantation we will check laboratory parameter of diabetes mellitus, insulin consumption, and adverse events and visit the patients in intervals before and after transplantation for 1 year.

##### Participants/Inclusion and exclusion criteria

inclusion criteria both gender 12-18 years old type one diabetes mellitus at least one positive auto antibody of T1DM in first 6 month of diagnosis Exclusion criteria malignancy simultaneous auto immune disorders pregnancy DKA presentation chronic disorder

##### Intervention groups

transplantation of placental mesenchymal stem cell from peripheral vein and with dose 2 million per new onset diabetic patient kilogram weight

##### Main outcome variables

HbA1c level; c-peptide level; T1DM auto antibodies; FBS and PPG; insulin requirement

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20171021036903N2**

Registration date: **2019-12-24, 1398/10/03**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-12-24, 1398/10/03**

Update count: **0**

#### Registration date

2019-12-24, 1398/10/03

#### Registrant information

##### Name

sedigheh madani

##### Name of organization / entity

EMRI

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8863 1298

##### Email address

s\_madani@razi.tums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2019-09-23, 1398/07/01

#### Expected recruitment end date

2021-03-21, 1400/01/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

phase I clinical trial placental mesenchymal stem cell therapy for the treatment of type 1 diabetes mellitus

## Public title

The safety of placental mesenchymal stem cell therapy for the treatment of type 1 diabetes mellitus

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

both gender 12-18 years old type one diabetes mellitus at least one positive auto antibody of T1DM in first 6 month of diagnosis

### Exclusion criteria:

malignancy simultaneous auto immune disorders pregnancy chronic disorder other than diabetes

## Age

From **12 years** old to **18 years** old

## Gender

Both

## Phase

1

## Groups that have been masked

*No information*

## Sample size

Target sample size: **10**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

ethic committee of tehran university of medical science

##### Street address

Bolvar keshavarz street, Tehran university of medical science

##### City

Tehran

##### Province

Tehran

##### Postal code

1417653761

#### Approval date

2018-01-28, 1396/11/08

#### Ethics committee reference number

IR.TUMS.VCR.REC.1396.4367

## Health conditions studied

### 1

#### Description of health condition studied

Diabetes Mellitus type 1

#### ICD-10 code

E10.9

#### ICD-10 code description

Type 1 diabetes mellitus without complications

## Primary outcomes

### 1

#### Description

daily insulin requirement

#### Timepoint

Before intervention and 1,3,6,12 month after intervention

#### Method of measurement

daily insulin requirement per kilogram weight

### 2

#### Description

HbA1c

#### Timepoint

Before and 1,3,6,12 month after intervention

#### Method of measurement

blood sample

### 3

#### Description

c peptide level

#### Timepoint

Before and 1,3,6,12 month after intervention

#### Method of measurement

blood sample

## Secondary outcomes

### 1

#### Description

life threatening major side effect

#### Timepoint

before and 1,3,6 ,12 months after intervention

#### Method of measurement

physical examination

## Intervention groups

### 1

#### Description

one time placental mesenchymal stem cell transplantation -which produced in endocrinology and metabolism research institute of Tehran university of medical science- from peripheral vein to T1Dm patients with 2 million per kilogram weight dose

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

TUMS hospitals-Endocrinology and metabolism research institute

**Full name of responsible person**

Seyyedeh Sedigheh Madani

**Street address**

Jalal al-ahmed

**City**

Tehran

**Province**

Tehran

**Postal code**

1411713137

**Phone**

+98 21 8863 1298

**Fax**

+98 21 8822 0052

**Email**

emrc@tums.ac.ir

**Web page address**<http://emri.tums.ac.ir/pages/mainPage.asp?l=S1M5P2C1>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Bagher Larijani

**Street address**

Jalal al ahmed

**City**

Tehran

**Province**

Tehran

**Postal code**

1411713137

**Phone**

+98 21 8863 1298

**Fax**

+98 21 8822 0052

**Email**

emrc@tums.ac.ir

**Web page address**<http://emri.tums.ac.ir/pages/mainPage.asp?l=S1M5P2C1>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

from clinical scientist budget

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Seyyedeh Sedigheh Madani

**Position**

Pediatric Endocrinology Subspecialist, Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Pediatrics

**Street address**

Jalal Al Ahmed

**City**

Tehran

**Province**

Tehran

**Postal code**

1411713137

**Phone**

+98 21 8863 1298

**Fax**

+98 21 8822 0052

**Email**

sedigheh\_madani@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Seyyedeh Sedigheh madani

**Position**

pediatric endocrinologist

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

**Street address**

Jalal al Ahmed

**City**

tehran

**Province**

Tehran  
**Postal code**  
1411713137  
**Phone**  
+98 21 8863 1298  
**Email**  
sedigheh\_madani@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
seyyedeh sedigheh madani  
**Position**  
pediatric endocrinology subspecialist student  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Pediatrics  
**Street address**  
jalal al ahmed  
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tehran  
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sedigheh\_madani@yahoo.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

Not applicable

### Title and more details about the data/document

donor and recipient demographic data and recipient follow up data

### When the data will become available and for how long

from beginning to the end of the study

### To whom data/document is available

principal manager /the supervisor professor /ethic committee

### Under which criteria data/document could be used

for analysis of the results and searching the reason of the probable side effects

### From where data/document is obtainable

PI

### What processes are involved for a request to access data/document

PI acceptance ----- ethic committee acceptance -----  
recording of this acceptance and the amount of data that should be given and the result that should be achieved

### Comments